REMARKS

In the Office Action, claims 33-36 are rejected under 35 U.S.C. §103 as allegedly unpatentable over U.S. Patent No. 5,252,295 (Gluchowski) in view of any of U.S. Patent No. 5,981,563 (Lowrey), U.S. Patent No. 5,942,545 (Samour), and U.S. Patent No. 5,236,904 (Gerstenberg). Applicants believe that the rejection is improper as detailed below.

Of claims 33-36, claim 33 is the sole independent claim. Claim 33 recites an ophthalmic formulation including a sterile aqueous carrier; and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. Claims 34-36 depend from claim 33.

In contrast, Gluchowski "does not teach a pharmaceutically active compound consisting essentially of phentolamine" as recognized by the Patent Office. See, Office Action at page 3. Therefore, Gluchowski, on its own, fails to anticipate or render obvious the claimed invention.

In an alleged attempt to remedy Gluchowski, the Patent Office states that "phentolamine is an imidazoline that is known in the art as an alpha receptor antagonist that is used to treat sexual dysfunction by its control of vasodilation as supported by Lowrey, Samour et al and Gerstenberg." Id. However, the Patent Office has improperly relied on Applicant's Specification in alleged support for the motivation or suggestion to combine Lowrey, Samour, or Gerstenberg with Gluchowski. Indeed, the Patent Office states:

> [a]pplicant states in the Specification that alpha 1 antagonists such as phentolamine that are used to treat sexual dysfunction...can be used as the claimed pharmaceutically active compound of the claimed invention...[and therefore] it would be obvious to one of ordinary skill in the art to modify the formulation of Gluchowski... *Id.*

Having relied on Applicant's disclosure of the claimed invention, clearly, the Patent Office has improperly applied "hindsight reasoning" in alleged support of the motivation or suggestion to combine the cited art teachings. Indeed, "[t]here must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge can not come from the applicant's invention itself." See, In re Oetiker, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). Therefore, the obviousness rejection should be withdrawn for at least this reason.

Even assuming that the references are properly combinable, Applicant believes that the alleged combined teachings fail to teach or suggest the claimed invention. As previously discussed, the claimed invention is directed to an ophthalmic formulation with an active phentolamine compound that can effectively reduce pupil size in dim light to improve vision in dim light and further minimize redness in the eye upon use. Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations. See, Published Specification (US2004/0176408), Examples 1 and 2 and Tables 1 and 2, beginning on page 6. Moreover, such unexpected results are further supported by an Affidavit of Gerald Horn, M.D. that was submitted in related patent application No. 09/854,414, a copy of which is attached herewith for consideration.

At best, Gluchowski indicates that oxazoline or imidazoline compounds are preferred (See, Gluchowski, col. 3, lines 39-41), but nowhere does Gluchowski specify an ophthalmic formulation that includes a pharmaceutically active compound consisting essentially of phentolamine and in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness as required by the claimed invention. Indeed, Gluchowski is directed to intraocular pressure and not reduction in pupil size, let alone the reduction of pupil size in dim light to improve vision in dim light where redness is further minimized as required by the claimed invention. Moreover, the secondary references fail to recognize the unexpected benefit of phentolamine in an ophthalmic formulation, let alone a phentolamine-based ophthalmic formulation that can effectively reduce pupil size in dim light to improve vision. Again, the secondary references are directed to the treatment of sexual dysfunction. Therefore, Applicants believe that the Patent Office has failed to establish a *prima facie* case of obviousness, and thus respectfully request that the obviousness rejection be withdrawn in view of same.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

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